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ב ק ש ה ל פ ט נ ט
Application For Patent

אני, (שם המבקש, מענו ולגבי גוף מאוגד - מקום התאגדותו)
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בעל אמצאה מכח חדין..... Operation of Law ששמה הוא
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שיטות לייצור מיקרו-מחטים


(בעברית)
(Hebrew)

MICRONEEDLES PRODUCTION TECHNIQUES

(באנגלית)
(English)

hereby apply for a patent to be granted to me in respect thereof

מבקש בזאת כי ינתן לי עליה פטנט

• בקשת חלוקה - Application of Division		• דרישת דין קדימה Priority Claim		
• מבקשת פטנט from Application	• בקשת פטנט מוסף - Application for Patent Addition	מספר/סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
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dated מיום	dated מיום			
יפוי כח : כללי P.O.A.: general/individual-attached/to be filed later-				
הוגש בענין..... filed in case				
המען למסירת מכתבים בישראל Address for service in Israel				
DR. MARK FRIEDMAN LTD. BEIT SAMUELOFF 7 HAOMANIM STREET 67897 TEL AVIV				
חתימת המבקש Signature of Applicant		היום 3 בחודש Mar שנת 2002 of the year This		
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שיטות לייצור מיקרו-מחטים

MICRONEEDLES PRODUCTION TECHNIQUES

Microneedle Production Techniques

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to techniques for producing hollow microneedles.

5 It is known to employ hollow microneedles for a wide range of applications including, but not limited to, fluid transfer through the skin of a subject. For the purpose of this application, microneedles are defined as needles with a maximum width dimension of no more than about 400 μm and a maximum height dimension of no more than about 2 mm. The microneedles
10 are formed as a one-dimensional, or more preferably two-dimensional, array projecting from the surface of a substrate.

Particularly advantageous forms of microneedles are described in co-pending, co-assigned U.S. Patent Applications Nos. 09/589,368, 09/589,369 and 09/677,175, and their precursor Israel Patent Applications Nos. 134997 and
15 138131, and their subsequent equivalent PCT publications, which are all hereby incorporated by reference as if set out entirely herein. The preferred forms of microneedles described therein provide a beveled ended microneedle, typically in the form of an asymmetric pyramid in which a fluid transfer bore intersects a sloped surface removed from the piercing point of each
20 microneedle.

While the aforementioned applications provide a full description of production of such microneedle forms using semiconductor production

techniques, it would be highly advantageous to be able to produce equivalent structures from polymer materials. It has been found, however, that conventional production techniques such as micro-injection-molding are not generally effective to fully reproduce such structures.

5 There is therefore a need for production techniques which would generate structures equivalent to those described in the aforementioned patent application from polymer materials.

SUMMARY OF THE INVENTION

10 The present invention is a method for producing a structure including a plurality of hollow microneedles projecting from a substrate, the method comprising: (a) forming a plurality of non-hollow microneedles on the substrate by use of plastic embossing or micro-injection-molding; and (b) performing a micro-ablation process to form a fluid transfer bore through each of the plurality of microneedles.

15 Preferably, the micro-ablation process includes performing ablation via a mask to simultaneously form a plurality of the fluid transfer bores.

Typically, a template used to produce the form used in the plastic embossing or micro-injection-molding process is generated by using a sample of hollow, or more preferably, non-hollow microneedles formed by
20 semiconductor production techniques such as those described in the above-referenced patent applications. The remaining details of both techniques are known in the art and will not be described here in detail.

Similarly, micro-ablation techniques are *per se* known. Registration between the two stages of the process may be achieved to the required accuracy by conventional reference-feature alignment techniques, such as are well known in the field of semiconductor production processes.

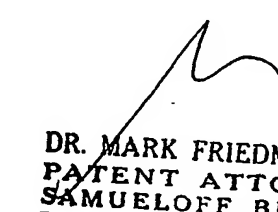
5 It will be noted that the method of the present invention may be applied to any polymer material which is suitable for the intended application. Preferred examples include, but are not limited to, polymers commonly referred to by the acronyms PMMA, PC, PS or PEEK and other biocompatible polymer materials.

WHAT IS CLAIMED IS:

1. A method for producing a structure including a plurality of hollow microneedles projecting from a substrate, the method comprising:

- (a) forming a plurality of non-hollow microneedles on the substrate by use of plastic embossing or micro-injection-molding; and
- (b) performing a micro-ablation process to form a fluid transfer bore through each of said plurality of microneedles.

2. The method of claim 1, wherein said micro-ablation process includes performing ablation via a mask to simultaneously form a plurality of said fluid transfer bores.


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